

September 9, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.

August 19, 1998

Richard P. Dumas
OPP/SRRD 3rd Floor
Crystal Station 1 Mail Code 7508W
2800 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Dumas:

This correspondence serves as our formal response to your letter dated July 20, 1998 regarding the Preliminary Risk Assessment of Sulfotepp (PC 079501).

Let us firstly state that we believe EPA has been completely fair in its dealings with Fuller System and the required due diligence to understand and minimize risk on the use of sulfotepp as a chemical and our Fulex Dithio Smoke as a product. We were pleased to learn of EPA's pro-active approach to learn about the use patterns and critical need to preserve this product in the dwindling arsenal of effective pest control products for the greenhouse grower. When crops turn to color or the canopy becomes dense, smoke is the *only* method of control available, typically toward the end of the crop, when costs and sales potential are at their highest.

While we have few specific comments regarding the scientific findings of the report for which these comments apply, we must caution that sulfotepp, while the chemical in question, is one component of our product. Smoke, the carrier and a common "element" of our world, has served as a strong deterrent and safety factor in the use pattern of our product. Humans and beneficial animals are innately aware of the dangers and irritability of smoke, and this has worked to preserve our quite exemplary safety record for the past 40 years of the use of sulfotepp as an effective insect control. In determining the most effective risk management strategies, we must not lose sight that sulfotepp is *only delivered in combination with smoke*, unlike virtually all other chemicals EPA evaluates and regulates.

Finally, these comments apply to Fulex Dithio Smoke only. While we understand the rationale behind combining the reports for both our product and that of Plant Products Inc., Plantfume 103, it must be noted that Fulex uses a 14% AI to weight while Plantfume uses 15% AI to weight. Therefore, findings for Fulex Dithio Smoke, which rely on Plantfume data are overstated by more than 7%.

We thank you for the opportunity to comment on your findings. If you have questions, comments or concerns, we can be reached at 781.933.0934 EST.

Horticulturally,

David Brock, Manager

To best follow this correspondence, we have elected to follow the package you sent on a page-by-page basis so that you can follow our comments in line with your document package. We hope this eases the burden on you and your staff to follow our comments.

1. We take issue with the final comment on the first page of the memorandum from R Griffin and J. Becker to K. Monk which states, "These studies may underestimate actual exposures." We would equally suggest that these studies may overestimate said exposures. For the EPA's Re-registration Branch HED to make this comment clearly suggests a bias.

Recommendation: This comment should be removed.

2. Regarding the various data citations, it would have been appropriate for us to have had sufficient time to gather and study each of these as part of this response. However, we trust the findings and accept the data as presented therein.
3. On page 5, various Epidemiological Studies were cited. Parts b and Parts c did not involve Fulex Dithio Smoke at all; the remaining reports may or may not have been due to Fulex Dithio Smoke. Therefore, of the 59 cases reported, a maximum of two (2), or 3.3% of reported incidents were attributable to Fulex Dithio Smoke. This may be due to the fact that this product has a 14% AI to weight and is not sold in California.

Recommendation: Notation should be made that Fulex Dithio Smoke has been responsible for a small (less than 4%) portion of reported incidents.

4. On page 7, B. Use and Usage, Part a, incorrectly states that sulfotepp, as formulated controls "related organisms, mollusks, fouling organisms and miscellaneous invertebrates". It is used *only* for insect control of common greenhouse insects: scale, mites, whitefly, aphids, mealybugs, thrips.

Recommendation: Remove the words "related organisms, mollusks, fouling organisms and miscellaneous invertebrates" from this section.

5. On page 7, B. Use and Usage, Part d, the application rate for Fulex Dithio Smoke is 7% less, or 0.0030 pounds AI per 1,000 cubic feet.

1. On page 7, B. Use and Usage, Part f, offers a possible use pattern. Many growers use the product only once, as it is quite effective (see part g – "in California, one or two applications of sulfotepp are also used per crop..."). For severe infestations, growers *may* follow a three day interval for three application use pattern. Rarely will a grower need more than three applications spread three days apart. This section suggests that a grower may use it every three days for an unlimited number of applications.

Recommendation: Change the wording to: "A typical use pattern is a single application; however, for severe infestations, an application rate of three applications, spread three to seven days apart typically gives complete control."

7. Page 8, part II Residential Use Patterns is incorrect. Sulfotepp is available of ruse by certified applicators in commercial greenhouses ONLY.

Recommendation: Change wording to: "Current labels prohibit application in residential greenhouses..."

8. Page 8, C.I.a. indicates there is a possible contact with sulfotepp *powder* (line 4). Sulfotepp is a liquid with a low vapor pressure. Per EPA, "since sulfotepp has a vapor pressure such that it acts as a fumigant", it does not precipitate to the plant but stays as a vapor. Part (1) is not possible, part (2) is

not possible as the material will not spill out unless the canister is actually tipped upside-down, which can not happen unless it is done purposefully, and parts (2) and (3), based on other assumptions made throughout the rest of the report and analysis, suggest an unlit canister has no chemical left in it. Further, there is no residue on the spent canister.

Recommendation: Since it was concluded that handling exposure risks were negligible and not analyzed further, no changes are required here.

9. In C. I. B, the $2.7\text{mg}/\text{m}^3$ was estimated as a reasonable example of exposure for handlers igniting a canister or entering following fumigation. These are incorrect assumptions for several reasons. Firstly, there is *no* exposure when starting a fumigation – there is no sulfotepp present. When igniting a canister, a user typically lights the can and moves up the aisle to the exit and ignites the next canister. The first canister just starts emitting smoke and sulfotepp as the user is at the next canister. In almost all instances, there is *NO* exposure during the ignition process. Also, many users of sulfotepp are using one canister per greenhouse, so there is only one ignition – the user is frequently out of the greenhouse when the can starts emitting smoke and sulfotepp.

The assumption of $2.7\text{mg}/\text{m}^3$ representing handler exposure possibly encountered when entering after

fumigation is also not correct in most instances. The typical use pattern is to light the product at the end of the work day and let it sit over night – 12 hours, at which point the greenhouse is ventilated. During this period, natural dispersion occurs and the concentration level will be less than at the four hour interval. It can be reasoned that if an application starts with 52.5mg ai and sees a level of $2.7\text{mg}/\text{ai}$ after four hours, then we could expect a level of 400x less at 12 hours, when ventilation procedures are followed by an applicator. This equates to a 0.0068 mg ai level for applicators following the ventilation criteria of “11 hours of nothing followed by one hour of fans” or “11 hours of nothing followed by two hours of passive vents” as outlined in the WPS.

Recommendation: Change wording to state: “exposure to handlers igniting the product is typically zero, especially for smaller operations lighting only a few cans or only one can of product. While the criteria used for analysis in this report assumes a reasonable level of exposure to handlers might be $2.7\text{mg ai}/\text{m}^3$, it is quite likely to be up to 400 times less concentrated.”

10. In part c, Other Assumptions, these are typically not correct for virtually all applications:

Applicators are typically exposed, if at all, for up to five minutes on the day of application; up to five minutes on the following day for venting; and then, if necessary, on the third to seventh day for a repeat application.

Exposure *does* depend on the size of the greenhouse and would range from under 3 minutes for small greenhouse to up to ten minutes for larger operations.

The premise that a handler lighting the canister is exposed to the same concentration as one entering to open vents is not only counter-intuitive, but as stated above in 9, wholly inaccurate.

Recommendation: Remove the false assumptions from the resultant calculations and risk assessments.

11. On page 9, Part II, Handler exposure and non-cancer risk estimates, most handlers would suggest that they are not sedentary by an estimates. Growers are active, hard-working laborers who are regularly involved at the aerobic level of exercise.

Recommendation: Change the activity factor to represent an aerobic worker versus a sedentary worker.

12. On page 11, the Table One, rightmost column can be re-calculated based on the correct assumptions outlined above in sections 4 - 11. These numbers would be increased by the following factors: 1x to 400x for air concentration levels, 6 - 10X for exposure duration, 2x for human activity factor, for a total increase of 12x to 8000x as follows:

Baseline (no respirator)	3.6/2.4
	2400/1600
Half-face OVRR	36/24
	520000/256000
Full-face OVRR	204/96
	2560000/1280000 (No meaningful MOE)
SCUBA	39600/20400
	No Meaningful MOE

Table One. Revised MOE For Handlers of Sulfotepp

Recommendation: Correct Table One as outlined above.

13. Section IV on page 12 can thus be corrected as follows:

At baseline, no protection MOEs range from 2400 to 3.6
With half-face OVRR, the MOEs range from 24 to 520,000
With full-face OVRR MOE's are 96 (approx. 100) or greater
With SCUBA MOEs are well above 100

Part b. states puncturing of cans which is not a factor with Fulex Products, only Plantfume 103. The duration of exposure is based on professional judgment from the manufacturer and actual visits and discussions with hundreds of growers and is therefore deemed much more accurate than EPA professional judgments.

In citing the AIHAJ study, which used 22 grams of sulfotepp, the label rate was estimated at 7 oz. per 20,000 cubic feet. This is wholly inaccurate, since the rate of application is 14% of this 7oz, or 0.98oz per 20,000 cubic feet (14% AI per canister, each of which weights 7 oz.).

Recommendation: Correct these inaccuracies.

14. Page 15, part C.1.c. assume scenarios which are simply unusual or not at all likely:

Post-application workers are assumed to be exposed to sulfotepp for 8 hours a day for a week or more. Considering the work day is then stated as eight hours, this assumes that a worker is in a post-treated greenhouse continuously for an entire week. This is simply not the case. For smaller operations, the worker is usually in a retail operation tending to customers and entering the greenhouse to collect more plants to be sold to the customers; else they are loading a truck outside, moving materials around or working in a related nursery or farm. They are never in the greenhouse for 40 hours per week. For larger operations, handlers move between houses, rarely staying in the same house for more than one or two hours. They also perform many of the tasks listed above. These scenarios over-state exposure by at least a factor of 2, more likely a factor of between four and eight.

Transfer coefficients are purely guesses. We could equally assume 100 and 1000 for low and high respectively. Further, 100% dermal exposure is a worst-case scenario that assumes a worker is spending all day (8 hours) rubbing exposed skin with sulfotepp residues. This is simply not reasonable

science. Also, since hand labor in a greenhouse is difficult and tiresome as well as rough on the hands, most workers use gloves. Combined, these realities should reduce exposure by a factor of at least 100x.

Recommendation: Reduce risk assumptions by a factor of 100x to represent real-life scenarios for the average grower and workers.

15. Based on the above, MOEs for Tables 2 and 3 can be calculated at rates up to 100 times that reported. Considering that additional applications are sometimes required by growers suggests that the amount of sulfotepp residue existing is not enough to kill the insects, otherwise additional applications would not be required. It is intuitive to assume that a concentration 18 *days* after application which gives an MOE of only 500 suggests that a required MOE of 100 is either too high or that the science used to calculate low and high levels is wholly inadequate.

The newly calculated MOEs using the correct assumptions above range from 30 to 1600 for dermal and inhalation risks as outlined in Tables 2 and 3, respectively. Total application MOEs would therefore range from 30 to 1400 for short and intermediate term rates as outlined in Table 4.

Recommendation: Correct Tables 2, 3 and 4 accordingly.

16. Risk Characterizations

II. Handlers

- a. **Inhalation Risks.** As outlined above the high and low level of sulfotepp concentration were significantly overstated by the incorrect assumptions. Accordingly, as stated in the preliminary report being studied, "In EPA's assessment, the risks appear acceptable at the lower estimated air concentrations with the use of an organic-vapor-removing respirator with a HEPA filter. The correctly calculated assumptions as presented above, suggest that the range of MOE is 96 - 204 confirms this. The NIOSH and Texas incident, the only one of its kind in the forty years of sulfotepp use, even suggests that during a second application, when inspectors were present, that the handler could smell something and had some symptoms, none of which were treatable or of concern, validates that the face respirator was effective. Further, in this *one* instance, the original incident was when circulating fans were on, increasing possible exposure. Circulating fans should not be on during a smoke fumigation. Finally, the EPA assessment that it would be cost prohibitive for SCBA, especially for small operations is very accurate. Many users of such applications are small family operations who could not do without sulfotepp but can not afford SCBA. Since OVRR with HEPA is adequate, we should leave well enough alone.

- b. **Dermal Exposure**

For dermal exposure, as shown above, MOEs were well above that required and handlers are currently required to wear protective gloves in any case. No action is necessary here.

Recommendations: Preserve the use of an OVRR with HEPA as the correct inhalation handler equipment for application and re-entry to activate ventilation equipment. If any consideration must be given to SCBA, which we feel is totally unwarranted, it should apply to only operations with 15 or more workers, which would mitigate the expense to the smaller grower operations. We also concur with many recommendations that labels should be tightened to recommend two applicators for small applications (less than 6 cans) and require it for large (greater than 6 cans) applications.

III. Postapplication Workers

- a. We accept the findings and concerns outlined herein, but suggest that few, if any, growers follow the criteria of ventilation of “24 hours with no ventilation”, even in cold climates. We concur that this should be removed as a possible ventilation criteria. Most growers ventilate after letting the sulfotepp/smoke combination to sit over night and many ventilate for longer than the 1 hour of fans and two hours of passive vents as required by WPS. Since the inert smoke has a foul odor (and Fuller System preserves this foul smell as a safety factor), most grower will ventilate for many hours, thus reducing possible risks as well. Further, since EPA has concluded that sulfotepp “has a vapor pressure such that it acts as a fumigant,” it is reasonable to expect levels of sulfotepp to dissipate with the opening and closing of doors, vents and other mechanisms which are practical during a greenhouse’s operation. Finally, if the residue or inhalation exposure were of any significance, insect populations would not re-appear, as occasionally happens, thus requiring a follow-up application. Common sense suggests that if it can’t affect an insect which would be exposed 24 hours a day, how can it have any significant effect on a human who would be exposed a maximum of 8 hours a day?.
- b. As outlined in sections 14 and 15, dermal exposure MOEs are grossly understated. Further, as EPA rightly concludes, many plants are shipped the morning following an application of sulfotepp and several hours of ventilation. Since the plants are then removed to the outside, workers are frequently in an open area where further dissipation occurs due to the low vapor pressure of sulfotepp. Further, many workers will also add products to a customers truck which may come from many greenhouses, several of which many not have had a sulfotepp treatment. Possible dermal exposure is further limited in this frequent scenarios.
- If post-application workers experience any discomfort or irritation, polypropylene gloves should be considered. However, since many workers typically do wear some type of glove, we feel this is not warranted at this time.
- c. Total exposure is significantly overstated as outlined above and a 38-hour interval is not practicable nor scientifically reasoned from the estimates offered. Ventilation is the key for the effective and safe use of sulfotepp. Removing the “24-hour doing nothing” possibility from the WPS would solve any possible exposure concerns. If EPA still considers inhalation risk to be of concern, increasing ventilation to “11 hours after application followed by 2 hour of fans” (versus one) or four hours of vents (versus 2) could be warranted. Since most applications are done at night, and ventilation occurs the next morning, this would cover most use patterns.
- d. We concur with the WPS comments and guidelines offered in this section. In 1991, as part of our re-labeling for Fulex Dithio Smoke, we *did* have the ventilation criteria listed on our label. When we re-labeled for WPS, we were told to remove these criteria and the applicator was to refer to their WPS handbook to find them. We objected at the time, stating “they are currently on the label, let’s leave them there and make the applicators job and use easier”. We were instructed to remove them from our label. On several occasions since then, we have recommended that they be re-added.

We further concur that two or more workers should be present re-entering the greenhouse to ensure voice or visual contact before inhalation levels are acceptable from one of the ventilation criteria.

We also concur that the posting warning labeling as outlined is appropriate.

We *do not*, however, agree with the dermal exposure possibilities and have refuted them substantially herein, citing that EPA’s (and others) assumptions are too restrictive by a factor of at least 100 times. No restricted entry interval is warranted for postapplication workers, other than the ventilation criteria already set forth by the WPS (excepting the “24-hour doing nothing” removal we endorse). Again, common sense prevails here – if it were of any significance to workers, multiple applications to control insects wouldn’t be required.

III. Exposure to Others

We concur with EPA in this area in almost all areas. Firstly, the use of sulfotepp *is* for commercial greenhouse use only. We agree that applications to houses that can not be sealed from homes, structures or buildings should be prohibited. (We should not assume “attached” poses harm, if it can be sealed off to prevent leakage). Finally, since a gas or vapor diffuses or dissipates evenly (Boyle’s Law), an area of 10 feet from a greenhouse would result in a 100% dissipation ratio. A 100 foot buffer would offer an MOE or dissipation ratio of 1/1000. We consider a 100 foot buffer to be adequate from possible exposure to sulfotepp. Since the inert smoke in sulfotepp smoke fumigants is quite foul, most exposure would be to an odor, not a chemical in all cases.

E. HED Recommendations

While we can’t argue with HED’s interest in further Toxicological Data or Exposure Data, Fuller System is in no position to financially supply said data. With the introduction of imidicloprid to the greenhouse market in 1995/6, sales of sulfotepp have been reduced significantly. We are in no position to fund or support any further studies.

In terms of part III, Fuller System will cooperate in any way possible to solicit and gather the Use Information requested and outlined. We believe we know some of these answers, but would be willing to work together with EPA, Plant Products and others to collect this information and compile it.

Conclusions

We have tried, as frankly and with common sense to respond to the preliminary report of EPA regarding the Occupational exposure and risk assessment of sulfotepp. In many cases outlined herein, we feel EPA has used far too stringent assumptions to make the conclusions stated. In the forty years we have offered sulfotepp, a highly toxic chemical mixed with a known inhalation risk, smoke, we have had an exemplary safety record. We consider the nature of the product, the fact that we regularly and candidly indicate to growers and users that it is highly toxic and requiring of respect and due diligence in its use have had a very positive and impressionable impact on its continued use as “old faithful.”

This does not, however, alleviate any of us from ensuring that good science, common sense, education, and continued feedback and communication come to bear on its continued availability and use as a most effective and important insect control methodology. We believe that growers are most aware of the risks in using the product and we have collectively, offered adequate and explicit warnings and recommendations through labeling and education.

As outlined herein, we can agree with EPA and other’s recommendation for several items:

- Improved labeling which outlines the WPS ventilation requirements *on the label itself*
- Removal of the “24 hours doing nothing” ventilation criteria as a possibility
- Requiring two-handlers for initiating ventilation criteria
- Requiring two handlers for applications of more than 6 cans
- Re-iterating non-use for residential greenhouses
- Dis-allowing use where attached buildings can not be sealed off
- Requiring a buffer zone when using sulfotepp in a residential area
- Increasing ventilation times to two hours of fans or four hours of passive vents after letting it sit for 11 hours.
- Requiring the use of a hand-held propane torch to light the sparkler so handlers can move quickly through the house when apply the product

- Requiring that fans be turned *off* during application to reduce spread and exposure when applying the product
- Requiring the canisters all be opened and unlit sparklers be inserted prior to igniting cans to ensure applicators can move quickly through the house
- Any other use recommendations that make sense.

Finally, we feel that the continued pressure on sulfotepp from marketplace forces, such as the introduction of fungus spore technology, imidicloprid and other new and novel chemistries may obviate the need for any further regulatory action from the EPA regarding this compound. Sales of sulfotepp are estimated to be down sixty percent from their uses of just three years ago. Supplies are not readily available and may cease within the next few years. And the ability for small companies such as Fuller System or Plant Products to continue to work under the regulatory, environmental, and public opinion scrutiny that continues to persist, may eliminate this product by default. While this does not obviate the need for further considerations to reduce risk, it rounds out the reality of the situation that now exists with sulfotepp.

We look forward to continuing this dialogue and working with EPA and others to adequately address and sufficiently ensure the continued safe use of this product for the commercial greenhouse grower.